



PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Bormann et al.

Application No. 09/806,322

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For: BIOLOGICAL FLUID FILTER AND
SYSTEM

Art Unit: 1723

Examiner: Krishnan S. Menon

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CLAIMS PENDING AFTER AMENDMENT IN RESPONSE TO THE OFFICIAL
ACTION MAILED AUGUST 5, 2002

1. A filter device for processing a biological fluid comprising:
 - a housing having an inlet and an outlet and defining a fluid flow path between the inlet and the outlet;
 - a filter disposed in the housing across the fluid flow path, the filter comprising:
 - a first filter element comprising a porous fibrous leukocyte depletion medium having a CWST of at least about 70 dynes/cm; and
 - a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less, said second filter element being disposed downstream of the first filter element;
 - wherein the filter is arranged to allow plasma to pass therethrough and substantially prevent the passage of leukocytes and red blood cells therethrough.
2. A filter device for processing a biological fluid comprising:
 - a housing having an inlet and an outlet and defining a fluid flow path between the inlet and the outlet;
 - a filter disposed in the housing across the fluid flow path, the filter comprising:
 - a first filter element comprising a porous fibrous red cell barrier and leukocyte depletion medium having a CWST of at least about 70 dynes/cm; and

a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less, said second filter element being disposed downstream of the first filter element;

wherein the filter is arranged to allow plasma to pass therethrough and substantially prevent the passage of leukocytes therethrough.

4. The device of claim 1, wherein the first filter element comprises melt-blown fibers.
5. The device of claim 1, wherein the first filter element comprises at least two layers.
6. The device of claim 1, wherein the first filter element has a CWST of at least about 90 dynes/cm.
7. The device of claim 1, wherein the filter includes no more than one membrane.
9. A system for processing a biological fluid comprising:
 - the device of claim 1; and
 - at least a first container and a second container, the first and second containers being suitable for use with biological fluid, wherein the device is interposed between the first and second containers.
10. A method for processing a biological fluid comprising:
 - passing a red blood cell- and leukocyte-containing plasma-rich biological fluid into a filter device comprising a filter including a fibrous leukocyte depletion medium and a membrane; and
 - collecting, from the filter device, a filtered plasma-rich biological fluid substantially free of leukocytes and red blood cells.
11. A method for processing a biological fluid comprising:
 - passing a leukocyte-containing plasma-rich biological fluid [through] into a filter device comprising a filter including a fibrous red blood cell barrier medium and a membrane; and

collecting, from the filter device, a filtered plasma-rich biological fluid substantially free of leukocytes.

12. A method for processing a biological fluid comprising:

processing a biological fluid to provide a supernatant layer comprising a leukocyte-containing plasma-rich fluid, and a sediment layer comprising a red blood cell-containing fluid;

passing the leukocyte-containing plasma-rich fluid into a filter device comprising a filter including a fibrous leukocyte depletion medium and a membrane; and

collecting, from the filter device, a filtered plasma-rich fluid substantially free of red blood cells and leukocytes.

13. The method of claim 12 wherein the leukocyte-containing plasma-rich fluid comprises a leukocyte- and platelet-depleted biological fluid.

14. A method for processing a biological fluid comprising:

depleting leukocytes and platelets from a red blood cell-containing biological fluid to provide a leukocyte- and platelet-depleted red blood cell-containing biological fluid;

processing the leukocyte- and platelet-depleted red blood cell-containing biological fluid to provide a supernatant layer comprising plasma and a sediment layer comprising red blood cells;

passing the supernatant layer through a filter device comprising a housing having an inlet and an outlet and defining a fluid flow path between the inlet and the outlet; and a filter disposed in the housing across the fluid flow path, the filter comprising a first filter element comprising a porous fibrous leukocyte depletion medium having a CWST of at least about 70 dynes/cm; and a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less, said second filter element being disposed downstream of the first filter element; wherein the filter is arranged to allow plasma to pass therethrough and substantially prevent the passage of leukocytes and red blood cells therethrough; wherein the filter further depletes leukocytes from the supernatant layer and substantially prevents the passage of red blood cells therethrough; and

collecting plasma-rich fluid in a container downstream of the filter device, wherein the plasma-rich fluid is substantially free of red blood cells and leukocytes.

17. The device of claim 1, wherein the second filter element comprises a porous membrane having a pore size in the range of from about 0.3 to about 3 micrometers.

18. The device of claim 7, wherein the second filter element comprises a porous membrane having a pore size in the range of from about 0.3 to about 3 micrometers.

19. The device of claim 2, wherein the second filter element comprises a porous membrane having a pore size in the range of from about 0.3 to about 3 micrometers.

20. A filter device for processing a biological fluid comprising:

a housing having an inlet and an outlet and defining a fluid flow path between the inlet and the outlet;

a filter disposed in the housing across the fluid flow path, the filter comprising;

a first filter element comprising a porous fibrous red cell barrier and leukocyte depletion medium having a CWST of at least about 70 dynes/cm; and

a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less, said second filter element being disposed downstream of the first filter element;

wherein the filter includes no more than one membrane, and is arranged to allow plasma to pass therethrough and substantially prevent the passage of leukocytes therethrough.

21. A method for processing a biological fluid comprising:

passing a plasma-rich biological fluid through a filter device comprising a housing having an inlet and an outlet and defining a fluid flow path between the inlet and the outlet, and a filter disposed in the housing across the fluid flow path, the filter comprising a first filter element comprising a porous fibrous leukocyte depletion medium having a CWST of at least about 70 dynes/cm; and a second filter element comprising a porous membrane having a pore size in the range of from about 0.3 to about 3 micrometers, the second filter element being disposed downstream of the first filter element;

wherein passing the plasma-rich biological fluid through the filter device depletes the biological fluid of leukocytes and red blood cells.

22. The method of claim 21, wherein passing the plasma-rich biological fluid through the filter device also depletes the biological fluid of platelets.

23. The method of claim 21, comprising passing about 500 ml to about 1000 ml of plasma-rich biological fluid through the filter device.

24. The filter device of claim 1, wherein the filter is arranged to substantially prevent the passage of platelets therethrough.

25. The filter device of claim 2, wherein the filter is arranged to substantially prevent the passage of platelets therethrough.

Amendment (Rev. 9/10/02)